

### REMARKS

Upon entry of the above amendment, claims 1, 5, 7-18, 22-27, and 46-59 will be pending, claims 3, 6, 21, and 28-45 having been newly canceled; claims 2, 4, 19, and 20 canceled in a prior amendment; and claims 46-59 newly added. Claims 1, 5, 23, 25, 26, and 27 are amended.

The amendment of claim 1 is supported in the specification at page 7, line 11. Claim 5 is amended to make it independent, incorporating the limitations of the claim from which it had depended. Claims 23 and 25-27 are amended to clarify their scope and/or fix informalities. New claims 46, 47, and 52-55 are supported, e.g., by original claims 5 and 8. New claims 48-51 and 56-59 are supported, e.g., by original claims 8 and 13. No new matter has been added.

All of the new claims belong in the restriction group currently under examination. Applicants request that they be examined in the present application.

#### Objection to claim 5

The Office action indicates that claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have amended claim 5 as suggested by the Examiner and ask that the objection be withdrawn. Claim 5 and the newly added claims that depend from claim 5 (i.e., claims 49, 53, and 57) are believed to be in condition for allowance.

#### Rejections under 35 USC § 103(a)

The Office action states that the rejection of claims 1, 7, 8, 12, 13, 17, 18, and 22 as allegedly obvious over Hadjantonakis et al. (Mech. Develop. 76:79-90, 1998), in view of Estes et al. (US Patent No. 7,423,135) is maintained "for reasons of record." According to the Office action at pages 3-4,

the Declaration under 37 CFR 1.132 filed February 16, 2010 is insufficient to overcome the rejection of claims 1, 7-18 and 72 (*sic*, 22) ... because the evidence shows the combination of mouse  $\beta$ -actin promoter and a human CMV enhancer, resulting in significantly higher level of luciferase expression as compared to a construct utilizing a

chicken  $\beta$ -actin promoter and a human CMV enhancer, and not to any species of CMV enhancer, that may include chicken, mouse or rat CMV. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims.

Applicants first point out that the Examiner has cited no basis for concluding that the evidence in the Declaration under 37 CFR 1.132 filed February 16, 2010 (the "Declaration") regarding experiments using human CMV enhancer is not representative of what would occur with other CMV enhancers, so that dismissal of the evidence as not being "commensurate in scope with the claims" is not warranted. Nonetheless, in order to move this case to allowance, Applicants have amended claim 1 to specify that the CMV enhancer is a human CMV enhancer. The Declaration, which is now unequivocally "commensurate in scope with the claims," provides objective evidence of unexpected results obtained with the presently claimed mouse  $\beta$ -actin promoter linked to a human CMV enhancer, compared results obtained with a chicken  $\beta$ -actin promoter linked to a CMV enhancer. The Office action does not dispute that the results described in the Declaration are unexpected and establish the nonobviousness of a claim limited to a construct or vector containing a mouse  $\beta$ -actin promoter linked to a human CMV enhancer. Accordingly, Applicants submit that claim 1 and all of its dependents (claims 7-18, 22-27, 46-48, 50-52, 54-56, 58, and 59) are nonobvious over the cited art.

Page 6 of the Office action states that the rejection of claims 1, 2 and 5 as unpatentable over Estes et al. and further in view of Debs et al. (US Patent No. 6,468,798) is withdrawn because "the nucleotide sequence disclosed by Estes et al. differs from the instantly claimed SEQ ID NO:2 by a single nucleotide." Applicants respectfully point out that this rationale pertains to claim 5, which specifies SEQ ID NO:2, but not to claim 1, which does not. (As noted in the Office action, the rejection as applied to claim 2 is moot, since claim 2 was previously canceled.) Claim 1 is patentable over the combination of Estes et al. and Debs et al. for at least the reason that nothing in either reference would lead one to expect the significant improvement in activity that Applicants achieved with the mouse  $\beta$ -actin promoter/human CMV enhancer combination specified in claim 1, as described in the specification and in the Declaration.

Page 6 of the Office action also addresses the rejection of claims 1, 7-11 and 14-16 as obvious over Estes et al. in view of Yano et al. (Cytotech. 16:167-178, 1994) and further in view of GenBank BC011083 (2002). Yano et al. and GenBank BC011083 are cited for their teachings regarding the c-Ha-ras oncogene. Nothing in the cited references would have suggested to one of ordinary skill in the art that a mouse  $\beta$ -actin promoter operably linked to a human CMV enhancer would exhibit the significantly increased activity demonstrated by Applicants in the specification and Declaration. As noted above, the new amendment to claim 1 ensures that the surprising results presented in the Declaration are unequivocally "commensurate with the scope of the claims." In view of these surprising results, Applicants submit that the claims are patentable over the cited references.

#### New claims 46-59

New claims 46-59 all depend directly or indirectly from claim 1 or claim 5, so are patentable for the reasons described above with respect to claim 1 or claim 5, respectively. In addition, each new claim includes further limitations that distinguish over the art. For example, claims 46 and 47 and their dependents (50, 51, 54, and 55) specify a particular sequence, either SEQ ID NO:4 or SEQ ID NO:2.

In view of the above, it is believed that all of the claims under examination are allowable. Applicants respectfully request that withdrawn method claims 23-27 be rejoined with the presently examined restriction group and fully examined on the merits. All of the other withdrawn claims have been canceled in order to speed allowance. This Reply is being filed with a Request for Continued Examination.

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The four-month extension fee of \$1730 and the Request for Continued Examination fee of \$810 are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 14875-0162US1.

Respectfully submitted,

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